



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5**

**DATE:** September 19, 2008

**SUBJECT:** U.S. EPA Questions/Clarifications on Draft Final Report, Peer Review of Michigan State University's PCB Exposure and Effects Studies in the Floodplain of the Kalamazoo River, September 1, 2008, Peer Review Panel

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**General – Sufficient Sample Size**

In several places the Panel states that sample sizes should be sufficient for use for some specified purpose. How is sufficient sample size determined? (2.2.1 Question 1 – “small sample sizes for some species/trophic levels (such as n=6 for earthworms)”, Table 1.1 in Charge – bird tissue data “only if a sufficient number of samples exist for a particular species”, 3. Use of invertebrate data “if the sample sizes are sufficient to provide meaningful estimates of prey tissue concentrations”, 5. Use of owl pellet analysis and passerine nestling dietary composition analysis “it must be demonstrated that sample sizes from the MSU studies are sufficient to support their use in dose modeling”)

**2.2.1. Question 1  
and 3.0 Panel's General Comments**

The statements regarding literature-based BAFs in the BERA are partially misleading. The BERA used site-specific BAFs for some terrestrial pathways (soil to earthworm, and soil to plant).

**Supplemental Issue 1a**

If the potential contribution of PCB exposure from aquatic insects is included in the area-specific risk assessments of bluebirds (or the equivalent for owls or other receptors with mixed terrestrial and aquatic prey), what procedure would the Panel recommend for calculating soil PRGs?

(Assume a post-remedial sediment value? Generate a matrix of soil – sediment PRGs combinations? Assume an exclusively terrestrial-based diet for soil PRG purposes?)

The statement “The Panel is concerned that the method used to determine the BAF factors may overestimate the BAF, resulting in higher “safe” values in the soil when calculating PRGs for clean up.” appears to be misstated. If starting with an acceptable dose to a receptor, an inappropriately high BAF would result in calculation of a soil PRG lower than the actual acceptable value.

### **MSU Shrew Studies**

“The panel felt that these data [PCB tissue levels in shrews and shrew trapping data] could be used to evaluate ... risks to shrews, that is, the shrews should be considered both a pathway and receptor species of concern. Each of these is described below.” For shrews as receptors, the draft report discusses PCB exposure and uptake, but does not address the strengths, limitations or uncertainties of the trapping data for providing inferences on field effects on shrew abundance (or, by extension, other small mammal abundances)

The Draft Interim Ecological Risk Assessment of Former Impoundment Soils, Oct. 5, 2001 Uptake submitted in response to the Panel’s 6/13/08 request for additional information, states that low HQs “... coupled with observations of viable populations of shrews and other small mammal species collected from the former Trowbridge impoundment, indicates that there are no measurable, population-level effects.”

The reported observations of viable populations are based on trapping success (number caught / number trap-nights), which is a catch per unit effort (CPUE) removal method. Thompson, et al. (1998) state that “Assumptions underlying the CPUE method will probably be difficult to meet in most field situations, and hence they should be carefully evaluated and tested before this technique is applied.”, and report that more than 70-80 % of a sampled population needs to be removed to obtain unbiased and precise CPUE estimates. The MSU trapping effort appears to have been designed to obtain sufficient data for comparison of biouptake of PCBs by small mammals, but not for estimating population abundances, as evidenced by cessation of trapping after a target number was collected.

What are the Panel’s comments on use of the MSU trapping data for comparing relative abundances of small mammals between Trowbridge and the reference location? For making inferences on population viability? And as a line of evidence for “no measureable, population-level effects”?

Thompson, W., G. White, and C. Gowan. 1998. Monitoring Vertebrate Populations. Academic Press, San Diego. 365 p.

### **Bluebird/house wren exposure (dietary dose) to other species (especially robin) exposure**

“...bluebird data may provide a bounding condition. ... Examination and contrast of feeding habits and ... sensitivity ... might lead to a conclusion that you can not extrapolate directly but

may be able to make inferences.” Please clarify the distinction between extrapolate and make inferences.

### **Time-related extrapolation issues**

Is the recommendation to predict future passerine and owl diets based on two to four general riparian successional patterns intended to be combined with the plausible future scenarios providing much more suitable habitat for earthworms? That is, should successional patterns be combined with projected hydrological conditions in a simultaneous analysis, or should each be considered separately in a sequential analysis? Similarly, should possible anthropogenic vegetative control (in addition to the indirect effects of dam removal) be evaluated in addition to successional and dam related changes?

### **Effects of Weathering of PCB mixture on Toxicity issue**

The Panel questions the assertion that BMFs cannot be applied directly to TEQs, because “Any changes in relative concentrations of individual congeners ... will influence concentrations (and BMFs) of both total PCBs and TEQs.” However, since congeners make unequal contributions to TEQ, processes that differentially affect congener concentrations will not equally affect total PCB and TEQ, that is, total PCB and TEQ values are unlikely to change in parallel. The divergence between change in total PCB and change in TEQ depends on the relative shift in congener patterns. The net change in TEQ is directly dependent on the aggregate change in congener-specific concentrations (multiplied by their respective TEFs), but the converse does not hold – a particular change in TEQ can be produced by many different combinations of congener-specific changes. This asymmetry is a rationale for not applying BMFs directly to TEQ (more explicitly, not applying an empirical TEQ BMF outside of the specific circumstance and place in which it was measured).

### **2.2.2 Question 2 and 2c and 4b Data interpretation – Pseudo Replication Issues**

Please expand on the comment that there are “issues with pseudo replication”, and clarify what is “far enough apart in space or time” to ensure statistical independence.

### **2c Evaluation of potential causal factors associated with any differences in passerine productivity**

Does the Panel conclusion that “it is not possible to make statistical inferences based on hypothesis testing about productivity on KRSS and compared to Ft. Custer.” apply as well to the separate recommendation to use a bioequivalence approach?

### **2.2.3. Question 3 Supplemental Issue 3a – Toxicity Reference Value**

The Panel response describes the EcoSSL TRV methodology as using the lower 95%CL of the geometric mean as the TRV value; however, this does not appear to be consistent with Eco-SSL

methodology. Eco-SSL SOP#6 Derivation of Wildlife Toxicity Reference Values (June 2007) OSWER Directive 92857-55 ([www.epa.gov/ecotox/ecossl/SOPs.htm](http://www.epa.gov/ecotox/ecossl/SOPs.htm)) does not describe confidence interval estimation, and CLs are not included in the derivation of PAH TRVs in Ecological Soil Screening Levels for PAHs, Interim Final (June 2007) OSWER Directive 9285.7-78 ([www.epa.gov/ecotox/ecossl/](http://www.epa.gov/ecotox/ecossl/)). Instead, the geometric mean PAH NOAEL TRV was not selected because it exceeded the lowest bounded LOAEL TRV for mortality, growth, or reproduction (“bounded” refers to linked NOAEL and LOAEL TRVs from a single study), which indicated the geometric mean NOAEL TRV was insufficiently protective. Instead, the PAH TRV was based on the highest bounded NOAEL that was lower than the lowest bounded LOAEL TRV of the studies included in the TRV derivation. Use of the lower confidence limit is part of the benchmark dose approach, however, the benchmark dose approach was not selected for Eco-SSL purposes (Eco-SSL SOP#6). Please clarify the Panel TRV recommendations.

**Kalamazoo River Superfund Site  
Peer Reviewer Draft Final Report  
MDEQ Questions to the Peer Review Panel**

MDEQ would like to express its appreciation to the Peer Review Panel for their efforts in producing the draft report. The depth of comments and analyses exceeded our expectations and provide substantial recommendations for agency consideration in the decision making process. With respect to the report, we offer the following for the Panel's consideration.

**Key Concerns of MDEQ**

1. Recommendations appear throughout the document. We request that all recommendations be moved from the discussion and presented in Section 4. It is the concern of MDEQ that recommendations presented in the discussion may be lost and/or have some measure of contradiction if they are not presented and discussed as a whole in the Recommendation Section.
2. Please rank the recommendations in order of importance, or at a minimum, classify recommendations as major or minor.
3. We request that the panel identify specific methods, wherever possible, to address the recommendations presented (e.g., identification of Mayfield method for recommendation 7).
4. Please identify which specific data sets from the MSU studies should be used in the proposed BERA-MSU cross comparison and what specific data sets should not be used based on the limitations identified. For example, comments regarding some MSU studies suggested data deficiencies such as small sample sizes and study design difficulties.
5. On page 43, the last two sentences of the Panel's Draft Response to 4b. and entitled "Panel's Draft Response - Inconsistent Statistical Methods" proposes use of the geometric mean, median and arithmetic mean in a manner that is contrary to other recommendations within the Panel's report and in disagreement with US EPA guidance (EPA. 1992d. *Supplemental Guidance to RAGS: Calculating the Concentration Term*. Office of Solid Waste and Emergency Response, Washington, DC. OSWER Directive No. 9285.7-081).
6. Because the Peer Review panel was not charged with review of the BERA, it appears that in some cases, the Peer Review group is not aware of all the site-

specific data used in its preparation. As an example, under Section 2.2.1, it should be noted that a substantial number of the BAFs used in the BERA food web models were derived using site-specific, co-located sampling and analysis of abiotic media and biota (e.g., soil + worms) and not simply literature references.

### **Editorial comments**

1. Please delete the following reference as it has no bearing on the Peer Review process:

Page 4, 3<sup>rd</sup> para. – "...because USEPA and KRSG have agreed that the aquatic-based ecological food web is unlikely to be the primary risk driver for management of formerly impounded sediments."

2. We suggest deletion of the following:

Page 5, 1<sup>st</sup> para., 1<sup>st</sup> sentence – "representing the Trustees"

Page 5, 2<sup>nd</sup> bullet – "and the USEPA"